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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|---|---|---|---|---|
| 10/615,651 | 07/09/2003 | Pu Zhou | 1001.1662101 | 9310 |

28075 7590 07/11/2007

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| EXAMINER | |
|---|---|
| HUSON, MONICA ANNE | |
| **ART UNIT** | **PAPER NUMBER** |
| 1732 | |

| MAIL DATE | DELIVERY MODE |
|---|---|
| 07/11/2007 | PAPER |

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**BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES**

Application Number: 10/615,651
Filing Date: July 09, 2003
Appellant(s): ZHOU, PU



David M Crompton
For Appellant

**EXAMINER'S ANSWER**

This is in response to the appeal brief filed 28 March 2007 appealing from the Office action mailed 2 August 2006.

**(1) Real Party in Interest**

A statement identifying by name the real party in interest is contained in the brief.

**(2) Related Appeals and Interferences**

The examiner is not aware of any related appeals, interferences, or judicial proceedings which will directly affect or be directly affected by or have a bearing on the Board's decision in the pending appeal.

**(3) Status of Claims**

The statement of the status of claims contained in the brief is incorrect. A correct statement of the status of the claims is as follows:

This appeal involves claims 1-11, 13, 35-41.

Claim 14 is withdrawn from consideration.

Claims 12 and 15-34 have been canceled.

**(4) Status of Amendments After Final**

The appellant's statement of the status of amendments after final rejection contained in the brief is correct.

**(5) Summary of Claimed Subject Matter**

The summary of claimed subject matter contained in the brief is correct.

**(6) Grounds of Rejection to be Reviewed on Appeal**

The appellant's statement of the grounds of rejection to be reviewed on appeal is correct.

**(7) Claims Appendix**

The copy of the appealed claims contained in the Appendix to the brief is correct.

**(8) Evidence Relied Upon**

| | | |
|---|---|---|
| 6,591,472 | Noone et al. | 07-2003 |
| 5,951,929 | Wilson | 09-1999 |
| 2004/0015150 | Zadno-Azizi | 01-2004 |
| 5,947,925 | Ashiya et al. | 09-1999 |

**(9) Grounds of Rejection**

The following ground(s) of rejection are applicable to the appealed claims:

Claims 1, 11, 13, and 35-41 are rejected under 35 U.S.C. 102(e) as being anticipated by Noone et al. (U.S. Patent 6,591,472).

Regarding Claim 1, Noone et al., hereafter "Noone," show that it is known to carry out a method of forming a catheter (Abstract) comprising providing a braid layer having a distal end and a proximal end, an inner lubricious liner positioned within the braid layer (Column 8, lines 33-34, 49-50); securing a first polymer segment over the braid layer, the first polymer segment being positioned proximal of the distal end of the braid layer, the first polymer segment having a distal end and a proximal end (Column 9, lines 16-17); cutting through the braid layer and the inner lubricious liner at a cutting position proximate the distal end of the first polymer segment and removing a portion of the braid layer that extends distally of the cutting position (Figures 5-6); and subsequent to cutting through the braid layer and the inner lubricious layer, securing a second polymer over the braid layer, the second polymer segment extending over the first polymer segment and extending distally of the cutting position (Figure 8, element 45, 145; Column 9, lines 19-20; Column 12, lines 9-11, 35-37, 52-61).

Regarding Claim 11, Noone shows the process as claimed as discussed in the rejection of Claim 1 above, including a method wherein the second polymer segment comprises in combination a proximal segment configured to overlay the braid layer, an intermediate segment configured to overlay the first polymer segment, and a distal segment configured to form a distal tip (Figure 8, element 75, 145).

Regarding Claim 13, Noone shows the process as claimed as discussed in the rejection of Claim 1 above, including a method wherein providing the braid layer comprises providing a braid layer that extends sufficiently distally of the cutting position to substantially prevent braid flaring at the cutting position (Figure 5, element 70).

Regarding Claim 35, Noone shows that it is known to carry out a method of forming a catheter (Abstract), comprising cutting a catheter subassembly at a cutting location (Figure 5, location 125), the subassembly having proximal and distal ends, an inner layer (Figure 5, element 65), a reinforcement layer on the inner layer (Figure 5, element 70), and a securement layer disposed over at least a portion of the reinforcement layer (Figure 5, element 100); removing the inner layer, the reinforcement layer, and the securement layer distally of the cutting location (Figure 6); and subsequent to removing the inner layer, the reinforcement layer, and the securement layer distally of the cutting location, securing a polymeric outer segment over at least the securement layer such that a portion of the polymeric outer segment

extends distally of the cutting location (Figure 8, element 45, 145; Column 9, lines 19-20; Column 12, lines 9-11, 35-37, 52-61).

Regarding Claim 36, Noone shows the process as claimed as discussed in the rejection of Claim 35 above, including a method further comprising forming a portion of the polymeric outer segment into a distal tip for the catheter (Figure 8, element 25).

Regarding Claim 37, Noone shows the process as claimed as discussed in the rejection of Claim 35 above, including a method further comprising assembling the catheter subassembly by providing an inner subassembly having the reinforcement layer disposed on the inner layer (Figure 5, elements 65, 70); and disposing the securement layer on the inner subassembly by securing a securement segment thereon (Figure 5, element 100).

Regarding Claim 38, Noone shows the process as claimed as discussed in the rejection of Claim 37 above, including a method wherein the reinforcement layer has a distal end, the securement layer has a distal end, and the step of disposing the securement layer on the inner subassembly is performed such that the distal end of the reinforcement layer extends distally beyond the distal end of the securement segment (Figure 5,elements 70, 100).

Regarding Claim 39, Noone shows the process as claimed as discussed in the rejection of Claim 35 above, including a method wherein the reinforcement layer comprises a braided member (Column 8, lines 49-51).

Regarding Claim 40, Noone shows that it is known to carry out a method of forming a catheter (Abstract) comprising providing a braid layer having a distal end and a proximal end (Column 8, lines 33-34, 49-50); positioning an inner lubricious liner within the braid layer (Column 8, lines 33-34, 49-50); securing a first polymer segment over the braid layer, the first polymer segment being positioned proximal of the distal end of the braid layer (Column 9, lines 16-17); cutting through the braid layer and the inner lubricious liner at a cutting location proximal of the distal end of the braid layer, thereby forming a catheter subassembly including the inner lubricious liner, the braid layer, and the first polymer segment, the catheter subassembly having a distal end defined at the cutting location (Figures 5-6); and securing a second polymer over the catheter subassembly, the second polymer segment extending over the first polymer segment of the catheter assembly and extending distally of the distal end of the catheter subasembly (Figure 8, element 45, 145; Column 9, lines 19-20; Column 12, lines 9-11, 35-37, 52-61), wherein the step of securing the second polymer segment over the catheter subassembly is performed subsequent to the step of cutting through the braid layer (Column 9, lines 19-20; Column 12, lines 9-11, 35-37, 52-61).

Regarding Claim 41, Noone shows the process as claimed as discussed in the rejection of Claim 40 above, including a method wherein providing the braid layer comprises providing a

braid layer that extends sufficiently distally of the cutting position to substantially prevent braid flaring at the cutting position (Figure 5, element 70).

Claims 2-5, 7, and 9-10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Noone, in view of Wilson (U.S. Patent 5,951,929).

Regarding Claim 2, Noone teaches the invention of claim 1 as discussed above, but does not expressly teach that the first polymer segment has a melting point that is at least about 10°F above a melting point of the second polymer segment. Wilson teaches using a blend of PEBA and approximately 30% $BASO_4$ (column 8, lines 32-33), which melts at a range of 385-400°F as the second polymer segment (column 8, lines 60-62) and ANRITEL™ as the first polymer segment, which melts at a temperature of 425°F (column 9, lines 21-36). Thus, Wilson teaches that the first polymer segment has a melting point that is at least 10°F (25°F) above the melting point of the second polymer segment. It would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to use Wilson's materials during Noone's method in order that the first polymer segment will not remelt upon application of the second polymer segment (Wilson, column 9, lines 41-50).

Regarding Claim 3, Noone shows the process as claimed as discussed in the rejection of Claim 1 above, but he does not show using shrink tubes. Wilson shows that it is known to carry out a method wherein securing the first polymer segment comprises positioning a heat shrink tube over the first polymer segment and applying sufficient heat and pressure to melt the first polymer segment (Column 7, lines 57-67; Column 8, lines 1-5). It would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to use Wilson's heat shrink tube during Noone's method in order to most efficiently bond the materials together.

Regarding Claim 4, Noone shows the process as claimed as discussed in the rejection of Claim 1 above, but he does not show using shrink tubes. Wilson shows that it is known to carry out a method wherein securing the second polymer segment comprises positioning a heat shrink tube over the second polymer segment and applying sufficient heat and pressure to melt the second polymer but not enough heat to melt the first polymer segment (Column 8, lines 52-65). It would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to use Wilson's heat shrink tube during Noone's method in order to most efficiently bond the materials together.

Regarding Claim 5, Noone shows the process as claimed as discussed in the rejection of Claims 1 and 4 above, but he does not show specific melting points. Wilson teaches that the first polymer segment has a melting point that is greater than about 400°F and the second polymer segment has a melting point that is less than about 400°F. Wilson teaches using a

blend of PEBA and approximately 30% $BASO_4$ (column 8, lines 32-33), which melts at a range of 385-400°F as the second polymer segment (column 8, lines 60-62) and ANRITEL™ as the first polymer segment, which melts at a temperature of 425°F (column 9, lines 21-36). It would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to use Wilson's specific materials for Noone's method in order for the final article to have the specific end-use chemical and physical properties.

Regarding Claim 7, Noone shows the process as claimed as discussed in the rejection of Claim 1 above, but he does not show a specific material. Wilson teaches the first polymer segment comprises a polyether-ester elastomer (column 9, lines 20-25). It would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to use Wilson's specific materials for Noone's method in order for the final article to have the specific end-use chemical and physical properties.

Regarding Claim 9, Noone shows the process as claimed as discussed in the rejection of Claim 1 above, but he does not show a specific material. Wilson teaches the heat shrink tube comprises a perfluoro (ethylene-propylene) copolymer (column 8, lines 50-54). It would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to use Wilson's specific materials for Noone's method in order for the final article to have the specific end-use chemical and physical properties.

Regarding Claim 10, Noone shows the process as claimed as discussed in the rejection of Claim 1 above, but he does not show a specific material. Wilson teaches the heat shrink tube comprises a perfluoro (ethylene-propylene) copolymer (column 8, lines 50-54). It would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to use Wilson's specific materials for Noone's method in order for the final article to have the specific end-use chemical and physical properties.

Claim 6 is rejected under 35 U.S.C. 103(a) as being unpatentable over Noone and Wilson, further in view of Zadno-Azizi (US 2004/0015150). Noone teaches the invention of claim 4 as discussed above, but fails to explicitly teach that the second polymer segment has a melting point that is about 350°F. Zadno-Azizi teaches a catheter outer coating (PEBAX) that has a melting point at about 350°F (paragraph 0177). It would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to use a material with Zadno-Azizi's specific melting point for Noone's method in order for the final article to have the specific end-use chemical and physical properties.

Claim 8 is rejected under 35 U.S.C. 103(a) as being unpatentable over Noone, in view of Ashiya et al (5,947,925), as stated in the paper mailed 21 September 2005. Noone teaches the invention of claim 1 as discussed above but fails to explicitly teach that the second polymer segment comprises a acetal resin/polyurethane blend. Ashiya et al., hereafter "Ashiya," teaches the second polymer segment comprises an acetal resin/polyurethane blend (column 6, lines 40-61, polyoxymethylene is an acetal resin). It would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to use Ashiya's specific material for Noone's method in order for the final article to have the specific end-use chemical and physical properties.

**(10) Response to Argument**

Since applicant has organized his remarks in sections, the Examiner will respond to the remarks in similar sections.

(A)

Applicant contends that Noone does not show securing a second polymer segment over a braid layer subsequent to cutting through the braid layer and the inner lubricious liner. Specifically, applicant contends that the examiner's interpretation of "securing a second polymer segment over the braid layer, the second polymer segment extending over the first polymer segment and extending distally of the cutting position" is impermissibly broad.

The examiner has interpreted that Noone shows a second polymer segment (45) over the braid layer (70) because the second polymer segment (45) is clearly over at least a cross sectional area of braid layer 70 (see Figure 8). Further, Noone shows that the second polymer segment also extends over the first polymer segment (80) and extends distally of the cutting position (Figure 5, element 125=cutting position; Figure 8, element 45 extends distally of cutting position), therefore meeting applicant's claim. In other words, the second polymer segment (45) is secured over the cut end of the catheter body, the cut end of the catheter body including exposed layers which make up the catheter. The examiner does not believe the interpretation is impermissibly broad, as the claimed adjective/adverb "over" can easily be broadly interpreted to indicate a wide variety of locations.

Applicant contends that placing a first thing to cover a surface of a second does not necessarily mean that the first thing is over the second, and further that " 'over' is a preposition that implies a direction; and when used with respect to an object such as a catheter,...the direction is understood by those of skill in the art to be in reference to the elongate central axis of the catheter. If a second layer is said to be over a first layer, the second

layer is understood to be at the same position along the axis as the first layer but further out radially." This is not persuasive because the claim does not require the second polymer segment to be in any particular relationship relative to an elongate central axis of the catheter. It is maintained that the term "over" does not necessarily require any axial component. For purposes of illustration only, two different elements can be placed "over" a tube's end to block the end, as illustrated below:

(i) (ii)

It is maintained that, similar to the Examiner's position, Figure (i) shows an element placed over the end of the tube, although the element does not have any axial component relative to the pipe itself.

With respect to claim 11, applicant contends that the rejection is not proper because the examiner has pointed to element 75 to show part of the second polymer segment. This is not persuasive, as this is merely a typographical error. Applicant will note that, when referring to Noone's second polymer segment in other claims (e.g. claims 1, 35, 40), the examiner consistently used Figure 8, element 45 and 145, while in the rejection of claim 11, "75" was accidentally typed instead of "45". The examiner apologizes for any confusion, but maintains that Noone does, in fact, show the claimed features of claim 11.

With respect to claims 13 and 35-41, applicant contends that these claims are allowable for the same reasons as claim 1. These reasons are not persuasive as discussed above.

(B)

(i)

Applicant contends that Noone and Wilson do not suggest the subject matter of claim 2 because although Noone discloses that the tip can be attached "in a manner well known in the art", he does not show attaching the tip of his catheter using welding. This is not persuasive because it is maintained that since Wilson shows attaching tips to catheters using welding or fusion (see Column 4, lines 65-67 and Column 7, lines 20-21), Noone could reasonably use

Wilson's welding of fusion to attach the second polymer segment. In other words, Wilson's method would have been a well-known method of attaching tips to catheters. It is maintained that different melting points for each segment would be optimal so that the first polymer segment remains stable (i.e. would not degrade or deform) during the fusion of the second polymer segment onto the first polymer segment (see, e.g. Wilson, Column 9, lines 41-50).

Applicant contends that Noone and Wilson do not suggest the subject matter of claim 3 because, although Wilson does disclose that using shrink tubing is a preferable way to secure polymer segments together, he does not specifically disclose that using shrink tubing is preferable because it is an efficient method for securing polymer segments together. This is not persuasive because the shrink tube allows simultaneous securing of three different polymer segments at one time (See Wilson, Column 8, lines 61-65). It is maintained that this is an efficient method of securing polymer segments together, relative to a method wherein various polymer segments are secured to each other sequentially.

(ii)

With respect to claims 2-5, 7, and 9-10, applicant contends that these claims are allowable for the same reasons as claim 1. These reasons are not persuasive as discussed above.

(C)

With respect to claim 6, applicant contends that these claims are allowable for the same reasons as claim 1. These reasons are not persuasive as discussed above.

(D)

With respect to claim 8, applicant contends that these claims are allowable for the same reasons as claim 1. These reasons are not persuasive as discussed above.

**(11) Related Proceeding(s) Appendix**

No decision rendered by a court or the Board is identified by the examiner in the Related Appeals and Interferences section of this examiner's answer.

For the above reasons, it is believed that the rejections should be sustained.

Respectfully submitted,

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